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August 9, 2000

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

CITIZEN PETITION
ANDA SUITABILITY PETITION

The undersigned submits this petition under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to permit the filing of an Abbreviated New Drug Application for a parenteral drug product that differs in container size from the reference listed drug.

A. Action Requested

By this petition we hereby request the Agency to permit the filing of ANDA 75-880 for 6% and 10% PremaSol™ – sulfite-free (Amino Acid) Injections in PL 146® Plastic Containers. These products are the same in active ingredients, dosage form, strength, route of administration and conditions of use as the referenced listed drug product, TrophAmine® (6% and 10% Amino Acid Injections) but differ in container size. The proposed 1000 mL and 2000 mL container sizes of 10% PremaSol™ – sulfite-free (Amino Acid) Injections in PL 146® Plastic Containers are larger than the 500 mL container size approved for TrophAmine® (6% and 10% Amino Acid Injections).

B. Statement of Grounds

ANDA 75-880 was submitted for 6% and 10% PremaSol™ – sulfite-free (Amino Acid) Injections in PL 146® Plastic Container on May 19, 2000. Three product configurations were proposed: a 500 mL container size of the 6% strength and 1000 mL and 2000 mL container sizes of the 10% strength.

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The reference listed drug, TrophAmine® (6% and 10% Amino Acid Injections) was approved in 500 mL glass containers. We were requested by the Office of Generic Drugs to file this ANDA suitability petition for the 10% strength in 1000 mL and 2000 mL container sizes because these are larger container sizes than approved for the reference listed drug.

Section 505 (j) of the Federal Food Drug and Cosmetic Act and 21CFR 314.92 (a) allow the submission of an ANDA for drug products that are identical in active ingredients, dosage form, strength, route of administration and conditions of use to a listed drug. The proposed 10% PremaSol™ – sulfite-free (Amino Acid) Injections in 1000 mL and 2000 mL PL 146® Plastic Containers are identical in active ingredients, dosage form, strength, route of administration and conditions of use to the reference listed drug, TrophAmine® (6% and 10% Amino Acid Injections). The inactive ingredients in the proposed product are the same as those in the reference listed drug in terms of identity and concentration except for the absence of the preservative sodium metabisulfite. 21CFR 314.94(a)(9)(iii) allows for the submission of an ANDA for parenteral drug products that differ from the reference listed drug in preservative, buffer or antioxidant provided that the applicant identifies and characterizes the differences and provides information demonstrating that the differences do not affect the safety of the proposed drug product. This information is provided in ANDA 75-880, Section IV.

Table 1 contains a comparison of the proposed generic drug products to the reference listed drug products. A comparison of the active and inactive ingredients of the proposed generic drug products and reference listed drug products is provided in **Attachment 1**. A side-by-side comparison of the proposed package insert labeling for the proposed generic drug products and the reference listed drug products is provided in **Attachment 2**.

Although the proposed 10% PremaSol™ – sulfite-free (Amino Acid) Injections are in larger container sizes (1000 mL and 2000 mL) than the reference listed drug products (500 mL), this difference raises no new issues of safety and effectiveness. The proposed products merely provide a greater number of single doses of the same drug ingredients in the same concentration as the reference listed drug (except for the absence of the preservative sodium metabisulfite in the proposed products). The proposed products are clearly labeled as pharmacy bulk packages which are intended for admixture and not for direct infusion. Thus there is no risk of a larger volume of solution being delivered to the patient than approved for the reference listed drug products.

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TABLE 1
COMPARISON BETWEEN PROPOSED GENERIC DRUG PRODUCTS
AND LISTED DRUG PRODUCTS

	PROPOSED DRUG PRODUCTS 6% and 10% PremaSol™ – sulfite-free (Amino Acid) Injections	LISTED DRUG PRODUCTS TrophAmine® (6% and 10% Amino Acid Injections)
Indications	Nutritional support of infants (including those of low birth weight) and young children requiring TPN via either central or peripheral infusion routes	Nutritional support of infants (including those of low birth weight) and young children requiring TPN via either central or peripheral infusion routes
Active Ingredients	Same as listed drug in identity and concentration. See list of ingredients and labeling in Attachments 1 and 2, respectively.	See list of ingredients and labeling in Attachments 1 and 2, respectively.
Inactive Ingredients	Same as listed drug in identity and concentration except for absence of preservative sodium metabisulfite. See list of ingredients and labeling in Attachments 1 and 2, respectively.	See List of Ingredients and labeling in Attachments 1 and 2, respectively.
Dosage Form	Injection	Injection
Strength	6% and 10% Amino Acid formulations. Same concentration of amino acids in weight per volume as the listed drug. See Attachment 1.	6% and 10% Amino Acid formulations
Route of Administration	Intravenous infusion	Intravenous infusion
Conditions of Use	Intended for admixture prior to administration. Typically admixed with dextrose, electrolytes and vitamins per individual patient prescription	Intended for admixture prior to administration. Typically admixed with dextrose, electrolytes and vitamins per individual patient prescription
Container Type	PL 146® Plastic Pharmacy Bulk Package[1] Containers	Glass Containers
Container Size	6% Strength – 500 mL 10% Strength – 1000 mL, 2000 mL	6% Strength – 500 mL 10% Strength – 500 mL

[1] A Pharmacy Bulk Package is a container of a sterile preparation for parenteral use that contains many single doses.

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C. Environmental Impact

The applicant requests a categorical exclusion from the preparation of an environmental assessment as provided under 21 CFR 25.31(a). There are no new drug substances in the proposed products. The proposed products will not be administered at higher dosage levels, for longer duration or for different indications than presently are in effect; therefore the use of the active moiety will not increase. No extraordinary circumstances exist regarding the proposed products to the applicant's knowledge.

D. Economic Impact

Available upon request of the Commissioner.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Mary Ellen Snyder for
Signature

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